

CLAIM

Sub A1
5 1. (as amended) A solid preparation with a coating around the core containing a gene-related drug for oral administration with releasability in lower digestive tracts, wherein the coating, not disintegrating in small intestines and has a double-coated structure of an inner layer comprising a cationic copolymer and an outer layer comprising an anionic copolymer.

2. (as amended) The solid preparation for oral administration according to claim 1 wherein the core containing the gene-related drug contains a binder as an additive.

3. (as amended) The solid preparation for oral administration according to claim 2 wherein the core containing the gene-related drug further contains an excipient as an additive.

4. (as amended) The solid preparation for oral administration according to claims 2 or 3 wherein the gene-related drug further contains one or both of a disintegrator and a saccharide as additives.

Sub A2
20 5. (as amended) The solid preparation for oral administration according to claims 2, 3 or 4 wherein the mixed ratio of the gene-related drug and the binder is 1:0.2-1:5 or the mixed ratio of the gene-related drug, the binder and the excipient is 1:0.2:0.01-1:5:1.

25 6. (as amended) The solid preparation for oral administration according to claims 4 or 5 wherein the mixed ratio of the saccharide contained in the core containing the gene-related drug is in

the range of 20-60 wt.%.

7. (as amended) The solid preparation for oral administration according to claims 4, 5 or 6 wherein the disintegrator contained in the core containing the gene-related drug is in the range of 2-15 wt.%.

8. (as amended) The solid preparation for oral administration according to any of claims 4-7 wherein the disintegrator is mixed for the production in the ratio of 1:0.05-1:10 against the content of the gene-related drug.

9. (as amended) The solid preparation for oral administration according to any of claims 3-8 wherein the excipient contained in the core containing the gene-related drug is in the range of 0.1-15 wt.%.

10. (as amended) The solid preparation for oral administration according to any of claims 1-9 wherein the gene-related drug contained in the core containing the gene-related drug is in the range of 0.1-50 wt.%.

11. (as amended) The solid preparation for oral administration according to any of claims 2-10 wherein the binder contained in the core containing the gene-related drug is in the range of 5-40 wt.%.

12. (as amended) The solid preparation for oral administration according to any of claims 4-11 wherein the disintegrators are crospovidone, alpha starch, sodium carboxymethyl starch, carmellose, calcium carmellose, sodium

5 carmellose, agar powder, sodium croscarmellose, crystalline
cellulose, low substituted hydroxypropyl cellulose, starch,
dextrin, hydroxyethylmethyl cellulose, hydroxypropyl starch,
hydroxypropyl cellulose, hydroxypropylmethyl cellulose,
polyvinylpyrrolidone, macrogol and mannitol.

13. (as amended) The solid preparation for oral
administration according to any of claims 4-12 wherein the
saccharides are monosaccharides and disaccharides such as
lactose, fructose, sucrose, glucose, xylitol, maltose,
mannitol and sorbitol, or polysaccharides and derivatives
thereof such as cellulose, crystalline cellulose, hydroxypropyl
cellulose, hydroxypropylmethyl cellulose, ethyl cellulose,
starch, dextrin, dextran, pectin and pullulan.

14. (as amended) The solid preparation for oral
administration according to any of claims 3-13 wherein the
excipients are light anhydrous silicic acid, ethyl cellulose,
carmellose, agar, magnesium aluminosilicate, calcium silicate,
magnesium silicate, cyclodextrin, starch, synthetic aluminum
silicate, synthetic hydrotalcite, titanium oxide, zinc oxide,
magnesium oxide, alumina magnesium hydroxide, magnesium
stearate, calcium stearate, aluminum silicate, talc,
crystalline cellulose and lactose.

15. (as amended) The solid preparation for oral
administration according to any of claims 3-13 wherein the
gene-related drugs are DNA or RNA, or modified compounds thereof,

or compounds thereof conjugated or bound to a carrier.

16. (as amended) The solid preparation for oral administration according to any of claims 2-15 wherein the binders are crystalline cellulose, gum arabic, sodium alginate, ethyl cellulose, agar, carboxyvinyl polymer, carmellose, gelatin, low substituted hydroxypropyl cellulose, starch, dextrin, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, pectin, polyvinylpyrrolidone, macrogol and methyl cellulose.

17. (as amended) The solid preparation for oral administration according to claim 15 wherein the carriers comprising a cationic polymer, cationic lipid, virus vector and phage.

18. (as added) The solid preparation for oral administration according to any of claims 1-14 and 16 wherein the gene-related drugs are one or more drugs selected from the group comprising a nucleic acid, oligonucleotide, antisense, triple helix forming oligonucleotide (TFO), ribozyme, decoy, plasmid, cosmid, P1 phage, YAC (yeast artificial chromosome), chromosome, aptamer and phage.